



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review--Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0650. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product
Establishments and Listing of Ingredients in Tobacco Products

OMB Control Number 0910-0650--Extension

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other things, a chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. The Tobacco Control Act created new requirements for the tobacco industry. Section 101 of the Tobacco Control Act amended the FD&C Act by adding, among others, sections 905 and 904 (21 U.S.C. 387e and 387d).

Section 905 of the FD&C Act requires the annual registration of any “establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.” Section 905 of the FD&C Act requires this registration be completed by December 31 of each year. The Secretary of Health and Human Services (Secretary) has delegated to the Commissioner of Food and Drugs the responsibility for administering the FD&C Act, including section 905. Section 905 of the FD&C Act requires owners or operators of each establishment to register: (1) their name; (2) places of business; (3) a list of all tobacco products which are manufactured by that person; (4) a copy of all labeling and a reference to the authority for the marketing of any tobacco product subject to a tobacco product standard under section 907 of the FD&C Act (21 U.S.C. 387g) or to premarket review under section 910 of the FD&C Act (21 U.S.C. 387j); (5) a copy of all consumer information and other labeling; (6) a representative sampling of advertisements; (7) upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and (8)

upon request made by the Secretary, if the registrant has determined that a tobacco product contained in the product list is not subject to a tobacco product standard established under section 907 of the FD&C Act, a brief statement of the basis upon which the registrant made such determination.

FDA collects the information submitted pursuant to section 905 of the FD&C Act through an electronic portal, and through paper forms (Forms FDA 3741 <https://www.fda.gov/media/77915/download> and 3741a <https://www.fda.gov/media/99863/download>) for those individuals who choose not to use the electronic portal.

FDA has also published a guidance for industry entitled “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments” (<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM191940.pdf>). This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

Section 904(a)(1) of the FD&C Act requires that each tobacco product manufacturer or importer submit “a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand” by December 22, 2009. This section applies only to those tobacco products manufactured and distributed before June 22, 2009, and which are still manufactured as of the date of the ingredient listing submission.

Section 904(c) of the FD&C Act requires that a tobacco product manufacturer: (1) provide all information required under section 904(a) of the FD&C Act to FDA “at least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment” of the Tobacco Control Act; (2) advise FDA in writing at least 90 days prior to adding any new tobacco additive or increasing in quantity an existing tobacco

additive, except for those additives that have been designated by FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use; and (3) advise FDA in writing at least 60 days of such action of eliminating or decreasing an existing additive, or adding or increasing an additive that has been designated by FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use.

FDA collects the information submitted pursuant to section 904(a)(1) and 904(c) of the FD&C Act through an electronic portal, and through a paper form (Form FDA 3742 <https://www.fda.gov/media/77661/download>) for those individuals who choose not to use the electronic portal.

In addition to the development of the electronic portal and paper form, FDA published a guidance entitled “Listing of Ingredients in Tobacco Products” (<https://www.fda.gov/media/101162/download>). This guidance is intended to assist persons making tobacco product ingredient listing submissions. FDA also provides a technical guide, embedded hints, and a web tutorial to the electronic portal.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to Chapter 9 of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))). On May 10, 2016, FDA issued that rule, extending FDA’s tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah tobacco, pipe tobacco, nicotine gels, and dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976) (“the final deeming rule”).

In the *Federal Register* of January 28, 2022 (87 FR 4622), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was not PRA related.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

FDA Form; Activity; Tobacco Control Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Recordkeeping	Total Hours
Tobacco Product Establishment Initial Registration and Listing; Form FDA 3741 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submissions); sections 905(b)-(d), 905(h), or 905(i)	200	1	200	1.6	320
Tobacco Product Establishment Renewal Registration and Listing; Form FDA 3741 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submissions); sections 905(b)-(d), 905(h), or 905(i)	2,572	1	2,572	0.16 (10 minutes)	412
Tobacco Product Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); section 904(a)(1)	16	1	16	2	32
Tobacco Product Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); section 904(c)	37	10	370	0.40 (24 minutes)	148
Obtaining a Dun and Bradstreet (D-U-N-S) Number	100	1	100	0.5 (30 minutes)	50
Total					962

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Since the publishing of the 60-day notice, the Consolidated Appropriations Act of 2022 (the Appropriations Act, Pub. L. 117-103), enacted on March 15, 2022, amended the definition of the term “tobacco product” in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) to include products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products that were not previously subject to the FD&C Act (e.g., products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act beginning on April 14, 2022. Based on this new authority the owners and operators of establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products containing NTN must register with the FDA and list all these tobacco products that they manufacture, prepare, compound, or process for commercial distribution. As such we have revised the estimates in the burden chart to account for products containing NTN.

The PRA burden estimates have been updated to fully incorporate the use of an electronic system known as Tobacco Registration and Product Listing Module Next Generation (TRLM NG) for submitting registration and product listing information to FDA. With the TRLM NG, manufacturers can enter information quickly and easily. For example, product label pictures can be uploaded directly. We anticipate that most, if not all companies, already have electronic versions of their labels for printing, sales, or marketing purposes.

Product listing information is provided at the time of registration. Currently, registration and listing requirements only apply to domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product. This includes importers to the extent that they engage in the manufacture, preparation, compounding, or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package. Foreign establishments are not required to register and list until FDA issues regulations establishing such requirements in accordance with section 905(h) of the FD&C Act. To account for the foregoing, we include both domestic manufacturing establishments and importers in our estimates.

The deadline for initial establishment registration and product listing for both statutorily regulated and deemed products has passed. However, pursuant to the new authority provided by the Appropriations Act, the FD&C Act now includes specific language that makes clear FDA has the authority the owners and operators of establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products containing NTN must register with the FDA and list all these tobacco products that they manufacture, prepare, compound, or process for commercial distribution.

FDA estimates up to 200 new establishments will submit one initial establishment registration and product listing report each year. Such new establishments potentially include manufacturers of NTN products, new vape shop locations that mix or assemble tobacco products on the market as of the final deeming rule effective date. The Agency estimates that up to 200

tobacco establishments will each submit 1 initial establishment registration and product listing report each year, which is expected to take 1.6 hours, for a total 320 burden hours.

FDA estimates that the confirmation or updating of establishment registration and product listing information as required by section 905 of the FD&C Act will take 10 minutes annually per confirmation or update per establishment. Based on FDA's experience with current establishment registration and product listings submitted to the Agency, the Agency estimates that on average 2,572 establishments will each submit one confirmation or updated report each year, which is expected to take 0.16 hour (10 minutes) for a total 412 burden hours.

FDA estimates that the submission of ingredient listings required by section 904(a)(1) of the FD&C Act for each establishment will take 2 hours initially. Ingredients may be submitted electronically through the Center for Tobacco Products portal or if unable to submit ingredients electronically then by mail using Form FDA 3742. We expect all 904(a)(1) tobacco ingredient submissions to have been received prior to November 8, 2018, for small manufacturers and large manufacturers, May 8, 2018, for cigarettes, cigarette tobacco, roll-your-own, smokeless tobacco, and deemed tobacco products. While all manufacturers have been expected to submit 904(a)(1) tobacco ingredient submissions, there may be a small number of firms that have missed this deadline. We are estimating approximately three manufacturers may have missed their deadline. This is based on estimates of how many late submissions FDA has received after the deadline. Because this burden estimate covers 3 years, we are dividing by 3, to yield 1 respondent as a yearly average for this estimate. Additionally, manufacturers for tobacco products containing nicotine that is not made or derived from tobacco must complete initial tobacco ingredient submissions for such products per section 904(a)(1) of the FD&C Act. Therefore, FDA estimates that 16 establishments will initially submit one report annually at 2 hours per report, for a total of 32 hours.

Submissions under section 904(c) of the FD&C Act are for any new product that is not yet on the market (e.g., if on the market due to deeming compliance period, deemed product

manufacturers should have submitted under section 904(a)(1) of the FD&C Act). This includes any statutorily regulated product that would receive a marketing authorization, any new deemed product not subject to the deeming compliance period, and any new NTN products not on the market as of April 14, 2022. For deemed product categories and NTN products, there is a portion of these applicants who will have reported their ingredients under section 904(a)(1) of the FD&C Act as most of these submissions are expected to be for products subject to section 904(a)(1) requirements.

Based on FDA's experience and the number of new products authorized to be introduced or delivered for introduction into interstate commerce submitted over the past 3 years, FDA estimates that 37 establishments will each submit 10 reports (1 every 6 months). FDA also estimates that the confirmation or updating of product (ingredient) listing information required by section 904(c) of the FD&C Act is expected to take 0.40 hour (24 minutes) for a total 148 burden hours. FDA estimates that obtaining a DUNS (data universal numbering system) number will take 30 minutes. FDA assumes that all new establishment facilities that will be required to initially register under section 905 of the FD&C Act would obtain a DUNS number. FDA estimates that up to 100 establishments that would need to obtain this number each year. The total industry burden to obtain a DUNS number is 50 hours.

FDA estimates the total burden for this collection to be 962 hours. We have adjusted our burden estimate, which has resulted in an increase of 132 hours to the currently approved burden. As a result, NTN products that were not previously subject to the FD&C Act (e.g., products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act beginning on April 14, 2022. Based on this new authority the owners and operators of establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products containing NTN must register with the FDA and list all these tobacco products that they manufacture, prepare, compound, or process for commercial distribution. As such we have revised the estimates in the burden chart to account for products containing NTN.

Dated: August 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-17248 Filed: 8/10/2022 8:45 am; Publication Date: 8/11/2022]